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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/566,944

02/22/2006

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/566,944 | Applicant(s) ZANK ET AL. | |
| | Examiner Elizabeth F. McElwain | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a process of producing fatty acids.

If this group is elected, then applicant is also required to elect one of each of the enzyme activities that are listed in a) and b).

Applicant is also required to elect one SEQ ID corresponding to the enzymes that are part of the elected invention. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group II, claim(s) 12 and 13, drawn to oil.

Group III, claim(s) 14, drawn to a process of mixing oils.

Group IV, claim(s) 15, drawn to feed, foodstuffs, cosmetics or pharmaceuticals.

Group V, claim(s) 16-18, 25 26, and 28-34, drawn to an isolated nucleic acid encoding a delta-5 elongase and organism transformed therewith.

If this group is elected, then applicant is also required to elect one SEQ ID from claim 16, and one SEQ ID from each of a) - c) in claims 17 and 18. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group VI, claim(s) 19, drawn to an isolated nucleic acid encoding a delta-6 elongase.

If this group is elected, then applicant is also required to elect one SEQ ID. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group VII, claim(s) 20, drawn to an isolated nucleic acid encoding a omega-3 desaturase.

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If this group is elected, then applicant is also required to elect one SEQ ID. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group VIII, claim(s) 21, drawn to an isolated nucleic acid encoding a delta-6 desaturase. If this group is elected, then applicant is also required to elect one SEQ ID. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group IX, claim(s) 22, drawn to an isolated nucleic acid encoding a delta-5 desaturase. If this group is elected, then applicant is also required to elect one SEQ ID. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group X, claim(s) 23, drawn to an isolated nucleic acid encoding a delta-4 desaturase. If this group is elected, then applicant is also required to elect one SEQ ID. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group XI, claim(s) 24, drawn to an isolated nucleic acid encoding a delta-12 desaturase. If this group is elected, then applicant is also required to elect one SEQ ID. If nucleic acid sequences and amino acid sequences are recited, then elect the nucleic acid sequence and corresponding amino acid sequence.

Group XII, claim(s) 27, drawn to an amino acid sequence encoding a delta-5 elongase.

1. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups II-XII lack the corresponding technical feature of Group I, which is the transformation of an organism with a combination of genes encoding the recited enzyme activities. Group II is drawn to oil, which can be made by a different method and does not require the process and genes of Group I, and Group III is drawn to mixing said oil, which also does not require the special technical feature of Group I. Group III is drawn to feed and other products that do not require the process of Group I. Groups V-XI are drawn to isolated nucleic acids encoding specified enzyme activities, which

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lack the corresponding technical feature of Group I, which requires the combination of multiple genes in a process, and each of said groups is distinct one from each of the other, wherein each is drawn to a nucleic acid encoding a different functional activity. And the invention of Group XII is drawn to an amino acid sequence encoded by the nucleic acids of Group V. The nucleic acid of Group V does not share a special technical feature with the polypeptide of Group XII.

According to the PCT Administrative Instructions, for molecules to be of similar nature, they need to share a common core structure and a common property or activity. Nor does the relationship of the polypeptides of Group I and the polynucleotides of Group II conform with Example 17 of the PCT Administrative Instructions. The instant claims are not directed to a single molecule, but encompass a family of molecules which are defined by a minimal structure. For these reasons, there is no shared technical feature between the nucleic acids of Group V and the polypeptides of Group XII.

Applicants are reminded that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the requirement for different searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth F. McElwain
Ph.D. Level Examiner
Art Unit 1638

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638